

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

In re Namenda Direct Purchaser Antitrust
Litigation

Case No. 1:15-cv-07488-CM (RWL)

**MEMORANDUM OF LAW IN SUPPORT OF
FOREST'S MOTION FOR LEAVE TO SUPPLEMENT THE EXPERT REPORTS
OF THE HONORABLE RODERICK MCKELVIE AND DR. LONA FOWDUR**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	FACTUAL BACKGROUND	1
A.	Neither the DRL Document—Nor Anything Like It—Was Produced During Discovery.....	1
B.	The DRL Document Supports the McKelvie Report With New and Important Evidence	3
C.	The DRL Document Confirms Dr. Fowdur’s Analysis of the Economic Motives Behind Settling the Patent Litigation.....	4
III.	ARGUMENT	5
A.	The Fowdur and McKelvie Supplemental Opinions Are Highly Probative to Critical Issues in the Case.....	6
B.	The DRL Document Was Unavailable to Forest During Discovery	7
C.	DPPs Will Not Be Prejudiced Because There is Ample Time Before Trial and Trial Will Not be Delayed.....	8
IV.	CONCLUSION.....	9

TABLE OF AUTHORITIES

Page(s)

CASES

<i>Capitol Records, LLC v. Escape Media Grp., Inc.</i> , No. 12-CV-06646, 2014 U.S. Dist. LEXIS 183098 (S.D.N.Y. May 28, 2014)	7, 8
<i>Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.</i> , 769 F. Supp. 2d 269 (S.D.N.Y. 2011).....	8
<i>Emig v. Electrolux Home Prods.</i> , No. 06-CV-4791, 2008 U.S. Dist. LEXIS 68811 (S.D.N.Y. Sep. 10, 2008).....	8
<i>In re Term Commodities Cotton Futures Litig.</i> , No. 12 CV 5126, 2018 U.S. Dist. LEXIS 66120 (S.D.N.Y. Mar. 23, 2018).....	5, 6, 7
<i>Northrup v. Werner Enter.</i> , No: 8:14-cv-1627-T-27JSS, 2015 U.S. Dist. LEXIS 105281 (M.D. Fla. Aug. 11, 2015)	9
<i>Outley v. New York</i> , 837 F.2d 587 (2d Cir. 1988).....	5, 6
<i>Powerweb Energy, Inc. v. Hubbell Lighting, Inc.</i> , No. 3:12CV220, 2014 U.S. Dist. LEXIS 52957 (D. Conn. Apr. 16, 2014)	6
<i>Queen v. Int’l Paper Co.</i> , No. 04-CV-342, 2006 U.S. Dist. LEXIS 26725 (N.D.N.Y. May 5, 2006).....	8
<i>Rmed Int’l v. Sloan’s Supermarkets</i> , 2002 U.S. Dist. LEXIS 23829 (S.D.N.Y. Dec. 11, 2002)	5, 9

STATUTES AND RULES

Fed. R. Civ. P. 37(c)(1).....	5
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I. INTRODUCTION

A central issue in this antitrust case is whether Forest's '703 patent case was strong, particularly in light of the *Markman* decision. Long after the close of discovery in this case, one of the parties to the patent litigation—Dr. Reddy's Laboratories—produced in the parallel Indirect Purchaser antitrust case a highly relevant document describing its contemporaneous view about the strength of Forest's '703 patent in view of the *Markman* decision. The newly-produced document supports the existing opinions of Forest's experts—namely, Judge McKelvie's opinion that Mylan's patent challenge was likely to fail and Dr. Fowdur's opinion that the Lexapro Amendment with Mylan did not delay generic entry. But the document is also unique because, unlike any discovery in the DPP case, it provides direct evidence of the generic challengers' views of the patent case. Accordingly, Forest respectfully moves the Court for leave to serve brief supplemental expert reports of Judge McKelvie and Dr. Fowdur (together totaling 9 pages), limited in scope to analysis of the Dr. Reddy's document. (The proposed supplemental reports are attached as Exhibit E and G.)

With about six months remaining to trial, DPPs will suffer no prejudice. While the supplemental opinions fall squarely within the scope of each expert's existing reports, if necessary, Forest is willing to make both Judge McKelvie and Dr. Fowdur available for additional deposition time on the supplements, and would not object to DPPs filing rebuttal expert reports on the same topic.

II. FACTUAL BACKGROUND

A. Neither the DRL Document—Nor Anything Like It—Was Produced During Discovery

In early 2008, Forest filed a patent infringement litigation against fifteen generic companies that filed Paragraph IV certifications against the '703 patent. Ultimately, each generic defendant

either withdrew its ANDA, was dismissed before filing an answer, or entered into a settlement agreement with Forest to resolve the case.

Both DPPs and Forest sought discovery in this case from generics that had challenged Forest's patent, concerning the merits and settlement of the patent case. Specifically, on January 5, 2017 DPPs issued a subpoena to Dr. Reddy's Laboratories, Ltd. and/or Dr. Reddy's Laboratories, Inc. (collectively, "DRL") seeking the production of "[a]ll documents and communications, regardless of date, concerning the patent litigation arising from Your ANDA for Generic Namenda, including, but not limited to: (a) the bases, merits, or likelihood of success of the litigation; (b) analyzing the scope or effect of any anticipated, proposed or actual outcome of the litigation, including any legal business or economic effects; (c) the decisions by You to defend, maintain, and/or settle the litigation, including any communications or any communications with agents. . . ." *See* Toto Decl., Ex. A at Exhibit B, Schedule A, § III, ¶ 6. Forest also served a subpoena on DRL on February 3, 2017, which encompassed the DPPs' request for this information. *Id.* at Exhibit A, ¶ 1.

Fact discovery closed on September 15, 2017. ECF No. 397. Neither DRL nor the other generic manufacturers who received similar subpoenas produced documents or testified regarding the strength of the '703 patent or their likelihood of success in the '703 patent litigation. Expert discovery took place from September 15, 2017 to November 10, 2017. ECF No. 397.

After the stay of the Indirect Purchaser Plaintiff ("IPP") case was lifted in September 2018, IPP served DRL (a defendant in the IPP case, but not the DPP case) with a document request. IPP requested all documents "concerning any potential or actual resolution, dismissal, and/or settlement of the patent infringement action, including analyses of the goals, costs, or benefits of any potential settlement and the costs and benefits of not settling any of the patent infringement

actions.” Toto Decl., Ex. B at § III.A, ¶ 9. In response, in November 2018 (a year after expert discovery had closed in the DPP case), DRL produced a document entitled “Dr. Reddy’s Laboratories Deal Approval Form,” which outlines DRL’s assessment of the *Markman* decision, its likelihood of success in the ’703 patent litigation, its anticipated litigation costs, and the rationale behind DRL’s decision to settle (the “DRL Document”). See Toto Decl., Ex. C, DRL (Namenda AT Litig)0012499. The DRL Document is unquestionably relevant and responsive to both DPPs’ and Forest’s prior document requests, pursuant to which there is a continuing production obligation.

B. The DRL Document Supports the McKelvie Report With New and Important Evidence

The expert report served by Judge Roderick McKelvie on October 9, 2017 (the “McKelvie Report”) assesses how a reasonable patent litigator would have viewed the merits of the claims and defenses to be presented in the ’703 patent litigation and responds to DPPs’ expert George Johnston. See Toto Decl., Ex. D, McKelvie Rep. ¶¶ 13, 14. Judge McKelvie opines that the *Markman* decision was very favorable to Forest and in light of the decision, that the generic defendants would have had a low likelihood of prevailing in the ’703 patent litigation. *Id.* at ¶ 58-60, 86-87. Further, Judge McKelvie concludes that because the *Markman* decision supported Forest’s position, each of the generic defendants that remained in the litigation settled. *Id.*

The DRL Document is highly relevant to these opinions, as it provides a contemporaneous assessment of the merits of the ’703 patent litigation by one of the generic defendants, and reaches the same conclusions as the McKelvie Report. Moreover, while Judge McKelvie considered the evidence available to him when drafting the McKelvie Report, documents or testimony regarding the generic manufacturers’ assessments of the impact of the *Markman* decision were not available. See *supra*, § II.A.

The proffered Supplemental Expert Report of Roderick McKelvie (the “McKelvie Supplement”) is a three-page report which analyzes the DRL Document and explains how the DRL Document further supports Judge McKelvie’s existing opinions. As set forth in the McKelvie Supplement, DRL’s contemporaneous assessment of the *Markman* decision supports the McKelvie Report’s conclusion that the generics “recognized the difficulty they would have faced in prevailing at trial.” Toto Decl., Ex. E, McKelvie Supp. at ¶ 5. Moreover, Judge McKelvie opines that the statements in the DRL Document are “consistent with the perspective of a reasonable patent litigator” and that “Mylan’s defenses were likely to fail, and the settlements that Forest reached with Mylan and the other generic defendants [were] borne out in the strength of Forest’s case on the merits of the patent litigation.” *Id.* at ¶ 9.

C. The DRL Document Confirms Dr. Fowdur’s Analysis of the Economic Motives Behind Settling the Patent Litigation

The expert report served by Dr. Fowdur on October 9, 2017 (the “Fowdur Report”) addresses, among other things, DPPs’ claim that Forest entered into anticompetitive patent settlement agreements with generic manufacturers to delay the entry of generic versions of Namenda IR. Toto Decl., Ex. F, Fowdur Rep. at ¶ 3. The Fowdur Report concludes that Forest made no payment to a generic manufacturer that caused delay in the entry of generic versions of Namenda IR, and criticizes the model that DPPs’ expert Einer Elhauge uses to calculate a but-for entry date. Professor Elhauge’s model relies, in part, on Forest’s perception of the strength of its patent case. *Id.* at ¶¶ 9, 24, 70-75. Dr. Fowdur opines that DPPs’ experts underestimate Forest’s perceived likelihood of success in the litigation because they do not consider that the *Markman* decision was “highly favorable” to Forest or that, because Mylan’s payoff for continuing to litigate was negative, it was plausible that Mylan would have dropped its Paragraph IV challenge if Forest refused to settle. *Id.* at ¶¶ 24, 70-75.

The six-page Supplemental Expert Report of Lona Fowdur Ph.D. (the “Fowdur Supplement”) evaluates the DRL Document from an economic perspective. Dr. Fowdur observes that, consistent with the position of Forest executives, DRL viewed the *Markman* decision to be a win for Forest, noting that the decision made the “non-infringement argument difficult to litigate” and that DRL was “unlikely” to win. Toto Decl., Ex. G, Fowdur Supp. ¶¶ 4, 5. This assessment supports Dr. Fowdur’s view that Forest perceived it had a strong patent, and directly contradicts DPPs’ estimate that Forest had perceived only a 40% chance of success. *Id.* at ¶ 9.

Additionally, similar to Mylan, DRL assessed that “continuing to litigate offer[ed] no upsides” because of the continued litigation costs and the number of generics that would enter in the “unlikely” event that DRL won the ’703 patent litigation. *Id.* at ¶¶ 6-8. These assessments similarly apply to other first filers, like Mylan, and provide strong support for Dr. Fowdur’s opinion that Dr. Elhauge was wrong not to account for the possibility that Mylan would have dropped its Paragraph IV challenge. *Id.* at ¶ 9-10.

III. ARGUMENT

Even when a party discloses expert opinions after the Court-ordered deadlines for the exchange of expert reports, that party is nonetheless permitted to rely on those opinions if the delay “was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1); *see also Outley v. New York*, 837 F.2d 587, 591 (2d Cir. 1988) (“Before the extreme sanction of preclusion may be used by the district court, the court should inquire more fully into the actual difficulties which the violation causes, and must consider less drastic responses.”); *In re Term Commodities Cotton Futures Litig.*, No. 12 CV 5126 (ALC) (KNF), 2018 U.S. Dist. LEXIS 66120, at *12-13 (S.D.N.Y. Mar. 23, 2018) (stating that “as a general rule, absent prejudice and bad faith, courts will not resort to exclusion”); *Rmed Int’l v. Sloan’s Supermarkets*, No. 94 CV 5587 (PKL) (RLE), 2002 U.S. Dist. LEXIS 23829,

at *11-12 (S.D.N.Y. Dec. 11, 2002) (refusing to grant motion *in limine* seeking to prevent expert from testifying about post-discovery supplemental expert report and holding that exclusion of testimony would be a “drastic remedy”). Under Rule 37, the following factors determine whether supplemental expert opinion may be offered at trial: (1) the importance of the evidence sought to be submitted; (2) the reasons for the delay in providing the evidence; (3) the prejudice to the opposing party from having to address the new evidence; and (4) the possibility of a continuance. *Outley*, 837 F.2d at 590; *Cotton Futures Litig.*, 2018 U.S. Dist. LEXIS 66120, at *13.

Here, each of the *Outley* factors demonstrates that allowing Forest to supplement the McKelvie and Fowdur Reports is substantially justified and harmless: (1) the assessment of the DRL Document is highly important to the case, (2) the delay is justified because the document was unavailable during discovery in the DPP case, (3) the Fowdur and McKelvie Supplements are brief and limited in scope, and (4) the October 21, 2019 trial date will be unaffected because DPPs have nearly six months to take depositions and submit their own expert analysis in advance of trial.

A. The Fowdur and McKelvie Supplemental Opinions Are Highly Probative to Critical Issues in the Case

The opinions set forth in the McKelvie and Fowdur Supplements are central to Forest’s liability and causation defenses and should be considered by the jury. *See Cotton Futures Litig.*, 2018 U.S. Dist. LEXIS 66120, at *16-17 (denying motion to strike supplemental expert report served after deadline for rebuttal expert reports in part because expert testimony was “vital to the plaintiff’s case”); *Powerweb Energy, Inc. v. Hubbell Lighting, Inc.*, No. 3:12CV220 (WWE), 2014 U.S. Dist. LEXIS 52957, at *14-15 (D. Conn. Apr. 16, 2014) (denying motion to strike supplemental expert report in part because the information party sought to strike was “central” to a “hotly contested and significant issue.”). DPPs have alleged that the settlement between Forest and Mylan, resolving the ’703 patent litigation, contained an anticompetitive reverse payment to

delay the entry of generic versions of Namenda IR. The strength of the '703 patent and likely outcome of the patent case are central to DPPs' theory that the alleged payment caused delay of generic entry. The DRL Document provides a unique perspective on these issues from the patent challengers' side of the '703 patent litigation, and no similar document has been produced in this case. Indeed, DPPs themselves sought this information from DRL during discovery. *See supra*, § II.A.

Moreover, DPPs' own experts have opined not only on the strength of the '703 patent and Forest's likelihood of success in the '703 patent litigation, but have also offered opinions regarding the likelihood of success that *the parties* to the patent litigation "perceived." *See* Toto Decl., Ex. H, Elhauge Rep. ¶¶ 59, 61; Toto Decl., Ex. I, Johnston Rep. ¶¶ 393-401. The DRL Document provides actual and direct evidence of such perceptions at the time. Because the DRL Document was not available to Forest's experts at the time they prepared their reports, Judge McKelvie and Dr. Fowdur responded to DPPs' experts without the benefit of contemporaneous evidence of the generic defendants' perceptions of the merits of the patent case. Now, for the first time, direct evidence is available showing that the generics (like Forest) believed that the *Markman* doomed the patent challenge.

B. The DRL Document Was Unavailable to Forest During Discovery

Courts have routinely recognized that supplemental expert reports are appropriate when they rely on newly discovered evidence. *See Capitol Records, LLC v. Escape Media Grp., Inc.*, No. 12-CV-06646 (AJN)(SN), 2014 U.S. Dist. LEXIS 183098, at *25 (S.D.N.Y. May 28, 2014) (finding supplemental expert submission was substantially justified where documents analyzed in supplement were produced "after [expert] could have possibly included them in his expert report."); *see also Cotton Futures*, 2018 U.S. Dist. LEXIS 66120, at *13 (noting that supplemental

expert reports are sometimes inappropriate under Rule 26(e) when they do not rely on “previously unknown or unavailable” information); *Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.*, 769 F. Supp. 2d 269, 278 (S.D.N.Y. 2011) (recognizing that supplemental expert reports are appropriate when they “rely on any information that was previously unknown or unavailable”); *Queen v. Int’l Paper Co.*, No. 04-CV-342 (FJS/DRH), 2006 U.S. Dist. LEXIS 26725, at *16-17 (N.D.N.Y. May 5, 2006) (granting motion for leave to supplement expert report relying on newly discovered information). Both Judge McKelvie and Dr. Fowdur offered opinions in their initial reports that are directly supported by DRL’s assessment of the ’703 patent litigation and settlement, and both experts would have assessed the DRL Document in their original reports had it been available to them at that time. The supplements are thus “substantially justified” by the recent availability of the DRL Document.

C. DPPs Will Not Be Prejudiced Because There is Ample Time Before Trial and Trial Will Not be Delayed

DPPs will not be prejudiced by Forest’s supplements to the McKelvie and Fowdur Reports, which together represent only nine pages of analysis (as contrasted with the nearly 1,000 pages of expert analysis already exchanged in this case). *See Capitol Records*, 2014 U.S. Dist. LEXIS 183098, at *25 (finding that any prejudice would be minimal where there was no risk of “surprise or trial by ambush”). The supplemental reports are limited in scope and explain how the DRL Document further supports the opinions set forth in the original reports. *See supra*, §§ II.B-C. Neither expert “expounds a wholly new and complex approach designed to fill a significant and logical gap in the first report” but rather “provides evidentiary details for [] opinion[s] expressed in [their] expert report[s].” *See Cedar Petrochemicals*, 769 F. Supp. 2d at 279-80 (denying motion to strike supplemental expert report that “support[ed] an initial position” and was “within the bounds” of original expert report); *Emig v. Electrolux Home Prods.*, No. 06-CV-4791 (KMK),

2008 U.S. Dist. LEXIS 68811, at *10 (S.D.N.Y. Sep. 10, 2008) (considering supplemental expert affidavit to the extent opinions in the affidavit were consistent with or contained in original expert report); *Commercial Data Servers, Inc. v. IBM*, 262 F. Supp. 2d 50, 61 (S.D.N.Y. 2003) (McMahon, J.) (finding that supplemental expert opinion would be admissible at trial where it was “substantially similar” to Rule 26 report).

Moreover, Forest will not object to DPPs’ experts submitting rebuttal reports limited to the same topic, or additional deposition time with Judge McKelvie and Dr. Fowdur regarding the supplements. *Rmed*, 2002 U.S. Dist. LEXIS 23829, at *13 (“any prejudice is easily cured by allowing plaintiff to depose [expert] if they so desire”).

Trial in this case is set to begin on October 21, 2019. ECF No. 688. If DPPs wish to depose these experts on the supplemental reports or submit rebuttal reports, they will have approximately six months to do so before trial commences. By comparison, the parties conducted all of expert discovery, consisting of twenty-seven expert reports and nineteen depositions, in about two months. Simply put, there is no reason that trial would be delayed or otherwise disrupted if the Court grants Forest leave to supplement the McKelvie and Fowdur Reports. *See Rmed*, 2002 U.S. Dist. LEXIS 23829, at *12 (“Allowing service of a new report authored by [previously disclosed expert] will not disrupt the trial, which is set to begin almost a month from now”); *see also Northrup v. Werner Enter.*, No: 8:14-cv-1627-T-27JSS, 2015 U.S. Dist. LEXIS 105281, at *4-5 (M.D. Fla. Aug. 11, 2015) (finding untimely disclosure harmless when provided six months before trial).

IV. CONCLUSION

For the foregoing reasons, Forest respectfully requests that the Court grant Forest leave to supplement the expert reports of the Honorable Roderick McKelvie and Lona Fowdur, Ph.D.

Dated: April 29, 2019
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Respectfully submitted,

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